DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 8, 2014

AALTO SCIENTIFIC LTD.
ROBERT BURDA
REGULATORY AFFAIRS MANAGER
1959 KELLOGG AVE.
CARLSBAD CA 92008

Re: K143026
Trade/Device Name: Audit® MicroControls™ Linearity FD Unsaturated Iron Binding Capacity
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, Reserved
Product Code: JJX
Dated: November 21, 2014
Received: November 21, 2014

Dear Mr. Robert Burda:

This letter corrects our substantially equivalent letter of November 21, 2014. We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143026

Device Name
Audit® MicroControls™ Linearity FD Unsaturated Iron Binding Capacity

Indications for Use *(Describe)*
The Linearity FD Unsaturated Iron Binding Capacity is an assayed quality control material intended to simulate human patient samples for use in determining linearity, calibration verification, and the verification of reportable range for unsaturated iron binding capacity.

Linearity FD Unsaturated Iron Binding Capacity is for In Vitro Diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

A. Submitter

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Contact Person

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Date of Summary Preparation

November 19, 2014

B. Device Identification

Product Trade Name:	Audit® MicroControls™ Linearity FD Unsaturated Iron Binding Capacity
Common Name:	Quality Control Material (Assayed and Unassayed)
Review Panel:	Clinical Chemistry and Clinical Toxicology Devices
Device Classification:	Class I, Reserved
Product Code:	JJX
Regulation Number:	21CFR862.1660

C. Device to Which Substantial Equivalence is Claimed

K130157 Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set

D. Intended Use

The Linearity FD Unsaturated Iron Binding Capacity is an assayed quality control material intended to simulate human patient samples for use in determining linearity, calibration verification, and the verification of reportable range for unsaturated iron binding capacity.

Linearity FD Unsaturated Iron Binding Capacity is for In Vitro Diagnostic use only.

E. Technical Characteristics Compared to Predicate Device

Characteristics	Audit® MicroControls™ Linearity FD Unsaturated Iron Binding Capacity (New Device)	Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set (Predicate Device, K130157)
Intended Use	The Linearity FD Unsaturated Iron Binding Capacity is an assayed quality control material intended to simulate human patient samples for use in determining linearity, calibration verification, and the verification of reportable range for unsaturated iron binding capacity. Linearity FD Unsaturated Iron Binding Capacity is for In Vitro Diagnostic use only.	The Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set is an assayed quality control material consisting of five levels of human based serum. Each level contains Beta-Hydroxybutyric Acid. These five levels demonstrate a linear relationship to each other for Beta-Hydroxybutyric Acid. It is intended to simulate human patient serum samples for purpose of determining linearity, calibration verification and verification of reportable range for Beta-Hydroxybutyric Acid. The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling and may be used as quality control material for Beta-Hydroxybutyric Acid. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The Audit® MicroCV™ Beta-Hydroxybutyric Acid Linearity Set should not be used for calibration or standardization of the Beta-Hydroxybutyric Acid assay. The Audit® MicroCV™ Beta-

		Hydroxybutyric Acid Linearity Set is “For In Vitro Diagnostic Use Only”.
Number of Levels per Set	5	5
Contents	5x1ml	5x1ml
Matrix	Human Based Serum	Human Based Serum
Type of Analytes	Clinical Chemistry	Clinical Chemistry
Form	Freeze Dried	Liquid
Storage	2-8ºC	2-8ºC
Open Vial/Recon Stability	30 days at 2-8ºC	40 days at 2-8ºC
Sterile	No	No
Analytes	Unsaturated Iron Binding Capacity	Beta-hydroxybutyric acid
Number of Analytes per Vial	1	1

F. Device Description

Audit® MicroControls™ Linearity FD Unsaturated Iron Binding Capacity product is an in-vitro diagnostic device consisting of five levels of freeze dried, linearity/QC material, containing additives in human serum. There are five levels labeled A,B,C,D and E which contain 1ml for each level.

Materials of human origin used in the manufacture of this linearity set have been tested using FDA approved methods and are found to be non-reactive for HbsAg and antibodies to HCV and HIV-1/2.

G. Value Assignment/Linearity

Each analyte value assignment for Level A through Level E is performed on Hitachi P-Modular by using the corresponding reagent. Each analyte was measured multiple times. The unsaturated iron binding capacity (UIBC) was measured and the mean value of the iron binding capacity was used to establish target iron binding capacity values at each level.

AMR
Unsaturated Iron Binding Capacity: 10-500 µg/dL

H. Summary of Performance Data

Stability studies have been performed to determine the reconstituted vial stability and shelf life for the Audit® MicroControls™ Linearity FD Unsaturated Iron Binding Capacity.

Shelf Life-Accelerated Stability
Accelerated stability studies were conducted to establish the shelf life stability claims. All supporting data is retained on file at Aalto Scientific, Ltd. Acceptance criteria were met to support the product claims as follows.

Shelf Life: 24 months, when stored unopened at 2-8ºC.

Shelf Life-Real Time Stability
Vials from two lots of finished product are stored at 2-8ºC (real time vials) and -80ºC (Day0 vials). Samples are taken at four different time points. The analyte values from the real time vials are compared to the Day0 vials (both tested in duplicate). The product is determined to meet its predicted shelf life if the % difference of the real time mean values compared to the Day0 mean value is within the acceptance criteria. All supporting data is retained on file at Aalto Scientific, Ltd.

Note: Real time studies are ongoing to support the shelf life of this product.

Reconstituted Vial-Accelerated Stability+Real Time Stability
Real time stability studies were conducted at the end of accelerated stability studies to establish the reconstituted vial stability claims. All supporting data is retained on file at Aalto Scientific, Ltd. Acceptance criteria were met to support the product claims as follows.

Reconstituted Vial Stability: Once a vial has been opened and reconstituted, the product will be stable for 30 days when stored tightly capped at 2-8º C.

I. Expected Values/Value Assignment

Value assignment of Audit® MicroControls™ Linearity FD Unsaturated Iron Binding Capacity have been performed to determine the expected values of the unsaturated iron binding capacity. Each unsaturated iron binding capacity value assignment for Level A through Level E is performed on Hitachi P-Modular by using the corresponding reagent. The unsaturated iron binding capacity was measured multiple times and the mean value of unsaturated iron binding capacity was used to establish target values at each level. The target ranges were calculated as +/-15% of the target mean values.

All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

Level A		Level B		Level C		Level D		Level E	
Target value	Target Range	Target value	Target Range	Target value	Target Range	Target value	Target Range	Target value	Target Range
75.7	64.4-87.1	185.5	157.7-213.4	297.3	252.7-341.9	403.7	343.2-464.3	525.1	446.3-603.8

J. Traceability

Materials are obtained from internally qualified vendors and are subject to an internal quality control process. Raw material information is retained on file at Aalto Scientific, Ltd.

K. Conclusions

Based upon the purpose of the device, the descriptions and labeling of the predicate device, the safety and efficacy, and the stability data generated, the product is substantially equivalent to the predicate device.